

**Workshop for Participants
CVM Pilot Project for
Electronic Submission of NCIEs**

Wednesday, August 13, 1997
10:00 AM - 5:00 PM

Old Town Holiday Inn
480 King Street
Alexandria, Virginia

Co-Sponsored by:
FDA Center for Veterinary Medicine
Animal Health Institute

AGENDA
AHI/CVM Workshop for Participants
CVM Pilot Project for Electronic Submissions
Wednesday, August 13, 1997

ATTENDANCE AT THIS WORKSHOP IS LIMITED TO REPRESENTATIVES FROM SPONSORS WHO HAVE SUBMITTED A LETTER OF INTENT TO PARTICIPATE IN THE CVM PILOT PROJECT FOR ELECTRONIC SUBMISSION OF NCIES.

This workshop will familiarize participants with the Pilot Project for Electronic Submission of NCIEs. It is your opportunity to experience the project first hand and have your questions answered. You are encouraged to send both regulatory and technical personnel to this workshop so that you will be ready to begin submitting electronic NCIEs on September 8, 1997.

MORNING SESSION

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| 10:00 AM | Welcome and Pilot Project Overview Dr. Woodrow Knight, <i>Center for Veterinary Medicine</i> |
| 10:15 AM | CVM Roles Ms. Elizabeth Parbuoni, <i>Center for Veterinary Medicine</i> |
| 10:30 AM | Sponsor Process and Roles Mr. Robert Rhorer, <i>Pfizer Inc</i> |
| 11:00 AM | CVM's NCIE processing Ms. Elizabeth Parbuoni |
| 11:15 AM | Security Measures Dr. Charles Andres, <i>Center for Veterinary Medicine</i> Ms. Susan Landis, <i>Pfizer Inc</i> |
| 11:30 AM | NCIE format Dr. Charles Andres Mr. Robert Rhorer |
| 12:00 NOON | Group Lunch |

AFTERNOON SESSION

- 1:00 PM Data Capture Forms**
Ms. Elizabeth Parbuoni
Ms. Martha McCrate, *Protiva, A Division of Monsanto*
- 1:15 AM Pilot Project Evaluation**
Dr. Charles Andres
Ms. Elizabeth Parbuoni
- 1:30 PM Question and Answer Session**
Moderator: Mr. Robert Rhorer
- 2:00 PM Demonstration –** Filling out an NCIE, creating the PDF with password encryption, creating e-mail message attaching NCIE, sending e-mail via Internet, CVM receives e-mail, opens PDF, creates receipt with password encryption, sends receipt message back to sponsor, sponsor receives and opens receipt
- 2:30 PM Refreshment Break**
- 3:00 PM Concurrent Training Sessions** (choice of hands-on demonstration or technical session)

Training Session One – Hands-on demonstrations
Interactive training – A Complete “How To”

Training Session Two – Technical session
Mr. John Stuurwold
Pharmacia & Upjohn
Details on setting Adobe® Acrobat® printer options, font choices, and methods for handling binary attachments to Internet e-mail

5:00 PM Adjourn

GENERAL INFORMATION

Registration – The registration fee for the workshop is \$85 and covers the cost of the registration, refreshment break and luncheon. To register for the training workshop, please complete the enclosed registration form and return it with your payment to AHI by Wednesday, July 23, 1997.

Please note the cancellation policy on the registration form. Unless requested, registration confirmations will not be sent.

Hotel Information – A guest room rate of \$122 single / \$142 double occupancy (plus applicable taxes) is available for attendees of the training workshop. To receive this rate, call the hotel at (703) 549-6080, and identify yourself as attending the Animal Health Institute meeting.

Your reservation should be made by Monday, July 28, 1997. After this date, reservations will be accepted on a space available basis.

Old Town Holiday Inn
480 King Street
Alexandria, Virginia
(703) 549-6080 telephone
(703) 549-0889 fax

Any changes in your hotel accommodations should be made directly with the hotel.

Transportation – The hotel is located in Olde Town Alexandria. Free shuttle service is available between the hotel and National Airport. The hotel is a 20 minute walk from the King Street Metro Station (blue and yellow lines). Parking at the hotel is \$7 per day.

Additional Information – Call Sandy Phelan at the Animal Health Institute at (703) 684-0011.

The following representatives from CVM and AHI member companies are responsible for planning and carrying out this training workshop.

Dr. Charles J. Andres, *Center for Veterinary Medicine*
Mr. Joseph R. Baldari, *Fort Dodge Animal Health*
Dr. Woodrow M. Knight, *Center for Veterinary Medicine*
Ms. Susan Landis, *Pfizer Inc*
Ms. M. Martha McCrate, *Protiva, A Division of Monsanto*
Ms. Elizabeth L. Parbuoni, *Center for Veterinary Medicine*
Ms. Sandra L. Phelan, *Animal Health Institute*
Mr. Robert G. Rhorer, *Pfizer Inc*
Mr. John E. Stuurwold, *Pharmacia & Upjohn*